

Amendments to the Claims:

1. (Currently Amended) A composition consisting essentially of a *Helicobacter pylori* membrane ~~fraction~~ protein in a form that is pharmaceutically acceptable for administration to humans form, wherein said protein has a molecular weight ~~that appears to be~~ of the order of 50, 32-35, or 30 kDa ~~after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.~~

2. (Canceled).

D 3. (Currently Amended) The composition of claim 1, wherein the ~~apparent~~ molecular weight of the protein is of the order of 50 kDa and the protein is obtainable by a process comprising the steps of in which:

- (i) extracting *H. pylori* bacteria ~~are extracted~~ with 1% n-octyl  $\beta$ -D glucopyranoside, followed by centrifugation to generate a bacterial pellet;
- (ii) recovering said a bacterial pellet ~~is recovered~~ and treating it ~~is treated~~ with lysozyme, followed by ~~and subjected to~~ sonication, and then followed by centrifugation to generate a centrifugation pellet;
- (iii) recovering said a centrifugation pellet ~~is recovered~~ and ~~it is subjected to~~ washing it with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation to generate a membrane fraction pellet;
- (iv) recovering the membrane fraction ~~consisting of the centrifugation pellet is recovered~~ and resuspending it ~~is resuspended~~ in aqueous medium to generate a membrane fraction;

- (v) subjecting the membrane fraction ~~is subjected~~ to an anion-exchange chromatography on a Q-Sepharose column in a 0-0.5 M NaCl gradient, followed by washing in 1 M NaCl;
- (vi) recovering the fraction eluted at the start of washing in 1 M NaCl and subjecting is recovered and it ~~is subjected~~ to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0-0.5 M NaCl gradient; and
- (vii) recovering the fraction eluted in 0.3-0.4 M NaCl ~~is recovered~~.

D 4. (Previously Presented) The composition of claim 3, wherein the protein has as N-terminal sequence the amino acid sequence as shown in SEQ ID NO:1.

5. (Currently Amended) The composition of claim 1, wherein the ~~apparent~~ molecular weight of the protein is of the order of 30 kDa and the protein is obtainable by a process comprising the steps of in which:

- (i) extracting *H. pylori* bacteria ~~are extracted~~ with 1% n-octyl  $\beta$ -D glucopyranoside, followed by centrifugation to generate a bacterial pellet;
- (ii) recovering said a bacterial pellet ~~is recovered~~ and treating it ~~is treated~~ with lysozyme, followed by ~~and subjected to~~ sonication, and then followed by centrifugation to generate a centrifugation pellet;
- (iii) recovering said a centrifugation pellet ~~is recovered~~ and it ~~is subjected to~~ washing it with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation to generate a membrane fraction pellet;

- (iv) recovering said the membrane fraction ~~consisting of the centrifugation pellet~~  
~~is recovered~~ and resuspending it is resuspended in aqueous medium to generate a  
membrane fraction;
- (v) subjecting the membrane fraction ~~is subjected~~ to an anion-exchange  
chromatography on a Q-Sepharose column in a 0-0.5 M NaCl gradient;
- vi) recovering the fraction eluted in 0.28-0.35 M NaCl ~~is recovered~~ and subjecting  
~~it is subjected~~ to an anion-exchange chromatography on a DEAE-Sepharose  
column, in a 0-0.5 M NaCl gradient; and
- (vii) recovering the fraction corresponding to the direct eluate ~~is recovered~~  
(absence of NaCl).

6. (Currently Amended) The composition of claim 1, wherein the ~~apparent~~  
molecular weight of the protein is of the order of 32-35 kDa and the protein is obtainable by a  
process comprising the steps of in which:

- (i) extracting *H. pylori* bacteria ~~are extracted~~ with 1% n-octyl  $\beta$ -D  
glucopyranoside, followed by centrifugation to generate a bacterial pellet;
- (ii) recovering said a bacterial pellet ~~is recovered~~ and treating it is treated with  
lysozyme, followed by and subjected to sonication, and then followed by  
centrifugation to generate a centrifugation pellet;
- (iii) recovering said a centrifugation pellet ~~is recovered~~ and ~~it is subjected to~~  
washing it with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation to  
generate a membrane fraction pellet;

- (iv) recovering the membrane fraction ~~consisting of the centrifugation pellet is-~~  
~~recovered~~ and resuspending it ~~is resuspended~~ in aqueous medium, advantageously  
in carbonate buffer pH 9.5, to generate a suspension;
- (v) subjecting the suspension obtained in (iv) to centrifugation ~~is centrifuged~~ at  
about 200,000 x g and recovering the supernatant ~~is recovered~~;
- (vi) reducing the pH of the supernatant obtained in (v) ~~is reduced~~ to about pH 7,  
advantageously by dialysing against phosphate buffer pH 7;
- (vii) subjecting the preparation obtained in (vi) ~~is subjected~~ to a cation-exchange  
chromatography on an SP-Sepharose column in a 0 - 0.5 M NaCl gradient,  
advantageously in a phosphate buffer pH 7; and
- (vii) recovering the fraction eluted in 0.26 - 0.31 M NaCl ~~is recovered~~.

7. (Previously Presented) A Helicobacter protein, or a polypeptide that is derived from  
the protein by fragmentation, in a substantially purified form, which is recognized by an  
antiserum raised against the protein of the composition of claim 1.

8 and 9. (Canceled).

10. (Previously Presented) A composition consisting essentially of a monospecific  
antibody that recognizes the protein of the composition of claim 1.

11. (Previously Presented) A composition consisting essentially of a monospecific  
antibody that recognizes the protein or polypeptide of claim 7.

12 and 13. (Canceled).

14. (Currently Amended) A diagnostic method for detecting the presence of Helicobacter in a biological sample comprising polypeptides or peptides, ~~according to which~~ comprises bringing the biological sample is brought into contact with the antibody of claim 10 so that an immune complex forms, removing the unbound material is removed, and detecting the immune complex formed between polypeptides or peptides of the sample and the antibody is detected.

D 15. (Currently Amended) A diagnostic method for detecting the presence of antibodies to Helicobacter in a biological sample comprising antibodies, ~~according to which~~ comprises bringing the biological sample is brought into contact with the protein or polypeptide of claim 1 or claim 7 so that an immune complex forms, removing the unbound material is removed, and detecting the immune complex formed between antibodies of the sample and the protein or polypeptide is detected.

16. (Currently Amended) A process for the purification of the protein of the composition of claim 1 from a biological sample, ~~according to which~~ comprises subjecting the biological sample is subjected to affinity chromatography using a monospecific antibody that recognizes said protein or polypeptide, and eluting said protein from said monospecific antibody.

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D<sup>2</sup> 17. (Currently Amended) An isolated immunogenic polypeptide fragment of the protein of the composition of claim 1.

18. (Currently Amended) A ~~The composition of claim 1, further~~ consisting essentially of (i) a *Helicobacter pylori* protein in a form that is acceptable for administration to humans, wherein said protein has a molecular weight on the order of 50, 32-35, or 30 kDa, and (ii) an adjuvant.

19. (Currently Amended) A ~~The composition of claim 1, further~~ consisting essentially of (i) a *Helicobacter pylori* protein in a pharmaceutically acceptable form, wherein said protein has a molecular weight on the order of 50, 32-35, or 30 kDa, and (ii) an additional *Helicobacter* polypeptide antigen.

20. (Currently Amended) The composition of claim 19, wherein the additional *Helicobacter* polypeptide antigen is comprises a *Helicobacter* urease, or an antigenic immunogenic subunit or fragment thereof.

21. (Withdrawn) The composition of claim 1, further consisting essentially of a *Helicobacter* urease, VacA, CagA/TagA, HspA, HspB, catalase, Hpa, Hpn, HopA, HopB, HopC, HopD, or an immunogenic subunit, fragment, or combination of any of these antigens.

22. (Currently Amended) The composition of claim 1, wherein said *Helicobacter* membrane ~~fraction~~ protein has a molecular weight ~~that appears~~ on the order of 50 kDa ~~after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.~~

23. (Currently Amended) The composition of claim 1, wherein said *Helicobacter* membrane ~~fraction~~ protein has a molecular weight ~~that appears~~ on the order of 32-35 kDa ~~after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.~~

24. (Currently Amended) The composition of claim 1, wherein said *Helicobacter* membrane ~~fraction~~ protein has a molecular weight ~~that appears~~ on the order of 30 kDa ~~after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.~~

D<sup>2</sup>  
25. (Withdrawn) A method of preparing a pharmaceutical composition, said method comprising combining the composition of claim 1 with an additional *Helicobacter* antigen.

26. (Withdrawn) A method of preparing a pharmaceutical composition, said method comprising combining the composition of claim 1 with an adjuvant.

27. (Withdrawn) A method of preparing a pharmaceutical composition, said method comprising combining the composition of claim 1 with pharmaceutically acceptable carrier or diluent.

28. (Currently Amended) A composition consisting essentially of a *Helicobacter pylori* protein in a form that is pharmaceutically acceptable for administration to humans form, wherein said protein has a molecular weight ~~that appears to be~~ of the order of 50, 32-35, or 30 kDa ~~after electrophoresis on a 10% polyacrylamide gel in the presence of SDS.~~

29. (Previously Amended) A composition consisting essentially of (i) a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS, and (ii) an additional *Helicobacter* polypeptide antigen, wherein said protein and said additional *Helicobacter* polypeptide antigen are in a form that is acceptable for administration to humans.

30. (Canceled).

D<sup>2</sup>  
31. (Withdrawn) A method of preparing a pharmaceutical composition, said method comprising combining a composition consisting essentially of a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS with an additional *Helicobacter* antigen.

32. (Withdrawn) A method of preparing a pharmaceutical composition, said method comprising combining a composition consisting essentially of a *Helicobacter pylori* protein having a molecular weight that appears to be of the order of 54 kDa after electrophoresis on a 10% polyacrylamide gel in the presence of SDS with an adjuvant.

D<sup>3</sup>  
33. (New) A composition consisting essentially of (i) a *Helicobacter pylori* membrane protein having a molecular weight of the order of 50, 32-35, or 30 kDa, and (ii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a form that is acceptable for administration to humans.



34. (New) A composition consisting of (i) a *Helicobacter pylori* membrane protein having a molecular weight of the order of 50, 32-35, or 30 kDa, (ii) an adjuvant, and (iii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a form that is acceptable for administration to humans.

35. (New) A composition consisting of (i) a *Helicobacter pylori* membrane protein having a molecular weight of the order of 50, 32-35, or 30, (ii) an additional *Helicobacter* polypeptide antigen, and (iii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a form that is acceptable for administration to humans.

36. (New) A composition consisting essentially of (i) a *Helicobacter pylori* membrane protein having a molecular weight of the order of 50, 32-35, or 30 kDa, (ii) an adjuvant, and (iii) an additional *Helicobacter* polypeptide antigen, wherein said composition is in a form that is acceptable for administration to humans.

37. (New) A composition consisting essentially of (i) a *Helicobacter pylori* membrane protein having a molecular weight of the order of 50, 32-35, or 30 kDa, (ii) an adjuvant, (iii) an additional *Helicobacter* polypeptide antigen, and (iv) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a form that is acceptable for administration to humans.

38. (New) A composition consisting essentially of (i) a *Helicobacter pylori* protein having a molecular weight of the order of 54 kDa, (ii) an additional *Helicobacter* polypeptide

antigen, and (iii) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a form that is acceptable for administration to humans.

39. (New) A composition consisting essentially of (i) a *Helicobacter pylori* protein having a molecular weight of the order of 54 kDa, (ii) an additional Helicobacter polypeptide antigen, and (iii) an adjuvant, wherein said composition is in a form that is acceptable for administration to humans.

40. (New) A composition consisting essentially of (i) a *Helicobacter pylori* protein having a molecular weight of the order of 54 kDa, (ii) an additional Helicobacter polypeptide antigen, (iii) an adjuvant, and (iv) a pharmaceutically acceptable carrier or diluent, wherein said composition is in a form that is acceptable for administration to humans.

41. (New) A *Helicobacter pylori* protein in a substantially purified form, wherein said protein has a molecular weight of the order of 50, 32-35, or 30 kDa.

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